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September 24, 2003

Via Federal Express

Document Processing Center (Mail Code 7407M)
Room 6428
Attention: 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency, ICC Building
1201 Constitution Ave., NW
Washington, DC 20460

COMPANY SANITIZED

Dear 8(e) Coordinator:

2,4-Dihalonicotinamide

This letter is to inform you of the results of an *in vivo* mutagenicity test recently conducted with the above referenced test material.

The test material was evaluated in the *in vivo* mammalian erythrocyte micronucleus test using 10 male Crl:CD®(ICR) BR mice per group. The test material was administered once by gavage, at dose levels of 0, 500, 1000, or 2000 mg/kg of body weight and the animals were sacrificed 24 or 48 hours after dosing. The test material was delivered in polyethylene glycol (PEG). Concurrent negative (vehicle) controls were included at both sacrifice time points, as well as a positive cyclophosphamide control at the 24-hour sacrifice time point. The *in vivo* mouse micronucleus test was negative.

The test material was administered to the mice as a solution at the 500 and 1000 mg/kg dose levels, and as a suspension at 2000 mg/kg. No clinical signs were detected at any time point in the 2000 mg/kg dose group. At the 1000 and 500 mg/kg dose levels, clinical signs including incoordination, tremors, hyperactivity and/or prostration were observed within approximately 10 or 12 minutes after dosing and persisted for less than an hour. These signs were not displayed after one hour post dosing or at any later time point. No clinical signs were observed in the negative or positive control groups. In the 1000 mg/kg dose group, 1/10 mice were found dead approximately 30 minutes after dosing.

Under these experimental conditions, the clinical signs described above appear to be reportable based upon EPA guidance given in the EPA TSCA Section 8(e) Reporting Guide (June, 1991).

Sincerely,

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CBI Substantiation

Support for [ ] claim of confidential business information for the information claimed as CBI is provided.

1. Confidential treatment should be afforded for ten years. Information should remain confidential until that time [ ]

2. No.

3. [ ] identity and the chemical identity [ ] are only disclosed to a second party [ ] under a nondisclosure (secrecy) agreement. [ ] has not otherwise disclosed the information claimed as CBI to other parties.

4. All documents relating to [ ]are stored in locked, limited-access facilities and designated as proprietary, trade secret or confidential. [ ] having access to the information are contractually prohibited from disclosing [ ] proprietary/confidential information outside the [ ].

5. No.

6. Yes. [ ] Disclosure of the CBI information would permit a competitor to specifically know and understand [ ] efforts and to forego the necessary time and expense to identify/develop this compound, thus capitalizing on [ ]. [ ] believes that a competitor's knowledge of the chemical identity [ ]interest in this compound would give a competitor several years advantage [ ] and would allow it to forego much of the R&D costs that it would otherwise have to bear. [ ].

7. a. No.

   b. Yes. The chemical identity [ ] would, potentially, disclose proprietary mixture [ ].

   c. Yes. Disclosure of [ ] would reveal the identity and source of the [ ].